The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 28

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte C. NEIL KITSON and
JENIFER L. THEWALT

Appeal No. 2004-0902
Application No. 09/780,060

MAILED
MAR 31 2004
U.S. PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

ON BRIEF

Before SCHEINER, ADAMS, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-9 and 14-19.[1] Claims 1-5 are representative of the subject matter on appeal, and read as follows:

> 1. A skin barrier replacement composition comprising an aqueous formulation of at least two lipids in a non-crystalline phase lamellar array which adopt a crystalline lamellar phase upon application to mammalian skin.

[1] Claims 1-19 and 22-40 are pending. Claims 10-13 stand as objected to as depending on a rejected base claim, and claims 22-40 stand withdrawn from consideration pursuant to a restriction requirement.

2. The composition of claim 1, comprising at least three lipids.

3. The composition of claim 2, wherein the at least three lipids comprise a ceramide, a saturated fatty acid and cholesterol.

4. The composition of claim 3, comprising bovine brain ceramide as the ceramide, palmitic acid as the saturated fatty acid and cholesterol in ratios by mol of from 1-5:1-5:1-5, respectively.

5. The composition of claim 3, comprising ceramide 2 as the ceramide, palmitic acid as the saturated fatty acid and cholesterol in ratios by mol of from 1-5: 1-5: 1-5, respectively.

The examiner relies upon the following references:

Kawada et al. (Kawada) 5,916,578 Jun. 29, 1999

Concise Encyclopedia Chemistry, Walter de Gruyter Berlin, New York, translated and revised by Mary Eagleson, pp. 599-600 (1994).

Claims 1-3, 6-9 and 14-19 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Kawada. In addition, claims 4 and 5 stand under 35 U.S.C. § 103(a) as being obvious over Kawada. After careful review of the record and consideration of the issues before us, we affirm the rejection under 35 U.S.C. § 102(e), but reverse the rejection under 35 U.S.C. § 103(a).

BACKGROUND

According to the specification:

> The instant invention provides a composition which when topically applied to the skin of a mammal reduces trans-epidermal water-loss and provides an improved epidermal barrier. The composition comprises an aqueous dispersion of at least two lipids, preferably at least three lipids, in a non-crystalline phase lamellar array, preferably bilayer membranes in the form of liposomes. These lipids adopt a crystalline lamellar phase upon application to

> mammalian skin which resists washing with mild detergents and water.

Id. at 2.

A crystalline phase, as defined by the specification, is "a physical state in which membrane lipids are organised [sic] on a lattice and have extremely reduced lateral and rotational mobility compared to the fluid arrangement of other mammalian cellular membranes. . . . For purposes of this invention, a crystalline phase formulation is defined where 70% or more of lipids by mass are in a crystalline phase." Id. at 4.

The specification teaches that:

> Application to the skin results in a rapid series of changes to the composition, all or some of which are responsible for inducing the phase transition of the lamellar arrangement. These changes include pH change, drying, packing and pressure changes, ionic strength change, temperature change; fusion of liposomes in close proximity; all of these changes may influence hydration state of the composition. All or some of these changes drive conversion from the non-crystalline phase to the crystalline phase. The process proceeds rapidly (at approximately the speed that water evaporates from the skin), leaves little or no "oily" or unsatisfactory feel to skin, and provides a long lasting trans-epidermal water-loss barrier.

Id. at 9.

DISCUSSION

1. Rejection under 35 U.S.C. § 102(e)

Claims 1-3, 6-9 and 14-19 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Kawada. The rejection is set forth below.

> Kawada [ ] teach[es] skin treatment compositions containing a liquid crystal phase containing a combination of a compound from a ceramide family, cholesterol and a fatty acid (e.g. palmitic acid) in the claimed proportions. See col. 1, lines 5-10; col. 15, Compositions 26 and 27. The lipid compositions of Kawada [ ] may be mixed with water. See col. 5, lines 9-15' col. 15, Compositions 26 and 27. With respect to Claims 6, 7 and 15, when the combination of lipids is mixed with aqueous phase by shaking the suspension, the liposomes that are formed are inherently multilamellar and have diameters from 100 to 3000 nm. See col. 17, lines 1-5 and "Concise Encyclopedia Chemistry", p.599. With respect to the limitation "crystalline lamellar phase" in Claims 1 and 8, this limitation is inherent in the prior art. If the composition of the instant claims adopt a crystalline lamellar phase either upon application to the skin or after the penetration into the stratum corneum, the compositions of Kawada [ ] will inherently behave the same because they contain the same ingredients as the claimed compositions. Under the doctrine of "inherency", prior art may anticipate a claim if it "inherently" possess all of the elements of the claimed invention, even if it "did not fully appreciate the uses, purposes, or properties of the product or process' created. General Electric Company v. Hoescht Celanese Corp., 740 F. Supp. 305, 312 (D. De. 1990). With respect to Claims 14, 16, 17, 18 and 19, the compositions 26 and 27 exemplified in col. 15, are free from all listed ingredients.

Examiner's Answer, pages 3-4.

Appellants argue that the examiner's reasoning that because Kawada teaches compositions containing some of the same component lipids the property that the compositions of Kawada adopt a crystalline lamellar phase upon application to mammalian skin "is both legally insufficient and scientifically incorrect." Appeal Brief, pages 3-4.

Appellants assert that the compositions of Kawada are complex mixtures that just happen to include some of the same components as the claimed compositions. Moreover, appellants contend, relying on the 132 declaration filed

November 21, 2002, by the inventors, compositions 26 and 27 both contain cholesteryl sodium sulfate, which does not crystallize to the same extent as cholesterol. In addition, according to appellants arguments and the declaration, those compositions also contain oleylamino-octadecane-1,3 diol, which has a cis-double bond in the chain. The declaration states at paragraph 3 that "[l]ipids with this stereochemistry are unlikely to crystallize," citing page 5 of the specification. In addition, appellants argue that the exemplified compositions in the present application have 125,000 times more water than the compositions of Kawada, which are hydrated with a small amount of water and subjected to freeze thaw cycles.

We recognize that in order for a prior art reference to serve as an anticipatory reference, it must disclose every limitation of the claimed invention, either explicitly or inherently. See In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1432 (Fed. Cir. 1997). As to inherency, the court has noted that "[u]nder the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates." Mehl/Biophile Int'l Corp. v. Milgraum, 192 F.2d 1362, 1366, 52 USPQ2d 1303, 1305 (Fed. Cir. 1999) (citations omitted). Moreover, "[w]here . . . the result is a necessary consequence of what was deliberately intended, it is of no import that the article's authors did not appreciate the results." Mehl/Biophile Int'l Corp., 192 F.2d at 1366, 52 USPQ2d at 1307.

We find that the examiner set forth a prima facie rejection and properly found that the teachings of Kawada anticipate claims 1-3, 6-9 and 14-19, and the rejection of those claims under 35 U.S.C. § 102(e) is affirmed.

Kawada teaches compositions 26 and 27, each comprising four ingredients, to which 200 μl of water were added. See Kawada, column 15. Composition 26 consists of 120 mg of (2S,3R)-2-oleoylaminooctadecane-1,3-diol (a ceramide), 75 mg of cholesterol, 75 mg of palmitic acid (a saturated fatty acid), and 30 mg of cholesteryl sodium sulphate. Composition 27 differs only in that a racemic mixture of the ceramide 2-oleoylaminooctadecane-1,3-diol is used. Thus, compositions 26 and 27 consist of all of the components set forth in claim 3, only differing in that they contain one extra component—cholesteryl sodium sulphate. Finally, Kawada teaches that its composition "enhances the moisture-retaining capacity of the stratum corneum;" therefore the compositions of Kawada have the same property of preventing water-loss that is a property of the compositions of the present invention. As the compositions taught by Kawada meet all of the limitations of claim 3, the examiner has met the burden of demonstrating that one of ordinary skill in the art would expect the property of adopting a crystalline lamellar phase upon application to mammalian skin to be an inherent property of those compositions, and the burden shifts to appellants to present evidence demonstrating that the claimed compositions are different from the compositions taught by Kawada. See In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

We have considered the declaration submitted by the inventors, as well as appellants' arguments, but we do not find them to be sufficient to rebut the prima facie case. First, the declaration sets forth opinions, but does not present any data demonstrating that compositions 26 and 27 of Kawada do not have the property of adopting a crystalline lamellar phase when applied to skin. Moreover, compositions 26 and 27 of Kawada contain four components, besides water, and thus contain only one additional component besides the three required by claim 3. While the declaration states that both compositions 26 and 27 of Kawada contain cholesteryl sodium sulfate, which, according to their research does not crystallize to the same extent as cholesterol, cholesteryl sodium sulfate is the component that is present in the smallest amount in those compositions. With respect to the presence of the cholesteryl sodium sulfate as well as the use of 2-oleoylaminooctadecane-1,3-diol as the ceramide, as set forth by the specification, a crystalline phase formulation is defined where 70% or more of lipids by mass are in a crystalline phase, and therefore complete crystallization is not required. Moreover, the declaration does not present evidence demonstrating that when applied to the skin, the compositions of Kawada do not achieve the property of adopting a crystalline lamellar phase to that extent. Finally, the specification teaches that several changes occur when the composition is applied to the skin, such as drying, pH changes, etc., all of which may affect the hydration state of the composition. Appellants have not supplied any data demonstrating that compositions 26 and 27 of Kawada would

not adopt a crystalline lamellar phase and that the amount of hydration of the composition is a critical factor.

Appellants argue further that Kawada provides data at column 14, lines 18-19, and column 13, lines 51-58, to show that the reference's liquid crystals do not crystallize. See Appeal Brief, page 5. Appellants conclude that "the compositions of Kawada are lamellar liquid crystals that do not crystallize, whereas the claimed invention is directed to non-crystalline phase lamellar lipid arrays (including but not limited to lamellar liquid crystals) that do undergo a phase transition to a crystalline lamellar phase." Id. (emphasis in original).

The above arguments are also not found to be convincing, as Kawada does not look at the ability of the compositions taught by that reference to crystallize when applied to mammalian skin. As noted above, the specification specifically teaches that

> [a]pplication to the skin results in a rapid series of changes to the composition, all or some of which are responsible for inducing the phase transition of the lamellar arrangement. These changes include pH change, drying, packing and pressure changes, ionic strength change, temperature change; fusion of liposomes in close proximity; all of these changes may influence hydration state of the composition. All or some of these changes drive conversion from the non-crystalline phase to the crystalline phase.

Specification, page 9.

The above passage demonstrates that it is application to mammalian skin that drives the phase change of the composition, and the teachings of Kawada demonstrating that their liquid crystals do not crystallize when heated and cooled

in a sealable silver pan do not address the issue of whether the reference's compositions would adopt a crystalline lamellar phase when applied to mammalian skin.

With respect to claims 6, 7 and 15, appellants argue that Kawada does not teach that liposomes form, or that "lipid particles of any particular type or size form." Appeal Brief, page 6. Appellants assert that "[t]he secondary reference teaches the formation of multilamellar liposomes of the asserted size range by shaking a mixture of phosphatidyl choline (egg lecithin), cholesterol and an acid component such as phophatidic acid. These compositions are not even remotely similar to the compositions of Kawada, and provide no insight into what necessarily is true of the compositions of Kawada." Id. at 6-7

As set forth above, we find that there is enough evidence supporting the prima facie rejection of anticipation, thus the property of forming liposomes would be an inherent property of the composition. The Concise Encyclopedia Chemistry was merely used in the rejection to support the rejection's contention that one of ordinary skill in the art would expect liposomes to form, especially in view of Kawada's teaching at column 17 that a white cream was obtained having small oily micelles. See Continental Can Co. USA v. Monsanto Co., 948 F.2d 1264, 1268, 20USPQ2d 1746, 1749 (Fed. Cir. 1991) Again, the Office does not have the facilities to test the compositions of the prior art, thus the burden is shifted to appellants to demonstrate that they are different. See In re Best, 562 F.2d 1252, 1254-55, 195 USPQ 430, 433 (CCPA 1977).

2. Rejection under 35 U.S.C. § 103(a)

Claims 4 and 5 stand rejected under 35 U.S.C. § 103(a) as being obvious over Kawada.

Due to the brevity of the rejection, it is set forth in its entirety below:

> Kawada [ ] applied as above. With respect to Claims 4 and 5, Kawada [ ] do[es] not teach using bovine brain ceramide or ceramide 2. however [sic], Kawada [ ] teach[es] that their composition "is used for a cosmetic or pharmaceutical product, it gives the same effect as a known natural ceramide extracted from bovine brain." See col. 11, lines 64-67. Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use bovine brain ceramide or any other ceramide used in cosmetic compositions for compositions of Kawada [ ] with a reasonable expectation of deriving the same cosmetic effect as set forth in the reference.

Examiner's Answer, page 4.

Appellants argue that the rejection fails to set forth why one of ordinary skill in the art would have been motivated to substitute bovine brain ceramide or ceramide 2 for the ceramide of Kawada. We agree.

The burden is on the examiner to set forth a prima facie case of obviousness. See In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598-99 (Fed. Cir. 1988). The test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." In re Gorman, 933 F.2d 982, 986, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991).

In the instant case, the recited optically active ceramides are central to the invention of Kawada. Also, Kawada teaches away from the use of bovine brain ceramide, teaching that it may no longer be used due to the outbreak of bovine

spongiform encephalitis (mad cow disease). See Kawada, col. 2, lines 46-50. Thus, we agree there is no motivation to replace the ceramides of Kawada with bovine brain ceramide or ceramide 2, and the rejection under 35 U.S.C. § 103(a) of claims 4 and 5 is reversed.

CONCLUSION

Because the Examiner's Answer properly sets forth a prima facie case of anticipation, the rejection of claims 1-3, 6-9 and 14-19 under 35 U.S.C. § 102(e) is affirmed. The rejection of claims 4 and 5 under 35 U.S.C. § 103(a), however, is reversed.

AFFIRMED-IN-PART; REVERSED-IN-PART

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